Complete Summary

GUIDELINE TITLE

Treating tobacco use and dependence. A clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

U.S. Department of Health and Human Services, Public Health Services. Treating tobacco use and dependence. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. 197 p. [311 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Tobacco dependence

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dentists
Health Plans
Managed Care Organizations
Nurses
Pharmacists
Physical Therapists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations along with a simple and flexible set of strategies that ensure that all patients who use tobacco are offered motivational interventions and effective treatments to overcome tobacco addiction.
- To include new effective clinical treatments for tobacco dependence that have become available since the original guideline was developed.

TARGET POPULATION

Adults, adolescents, and children who use tobacco

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Screen for tobacco use
2. Assess willingness to quit

Treatment

1. Brief clinical interventions, including patient education, motivational techniques to promote quitting, relapse prevention (minimal practice and prescriptive) for the patient who has recently quit
2. Counseling and behavioral therapy
    - problem solving skills/skills training (techniques on achieving and maintaining abstinence)
    - social support (clinician-provided encouragement and assistance)
    - aversive smoking techniques, such as rapid smoking or rapid puffing
3. Pharmacotherapy: First-Line
    - Bupropion SR (sustained released bupropion)
    - Nicotine gum
    - Nicotine inhaler
    - Nicotine nasal spray
    - Nicotine patch (over-the-counter, prescribed)
4. Pharmacotherapy: Second-line
    - Clonidine

- Nortriptyline
- Combination nicotine replacement therapy

NOTE: pharmacotherapies considered but not recommended include:

- Antidepressants other than bupropion SR and nortriptyline
- Anxiolytics/benzodiazepines/beta-blockers
- Silver acetate
- Mecamylamine

5. Advice on weight gain after smoking cessation
6. Clinician training

MAJOR OUTCOMES CONSIDERED

- Tobacco abstinence for at least 5 months
- Morbidity and mortality due to tobacco use
- Societal cost of tobacco use

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The updated guideline is based on two systematic reviews of the available scientific literature. The first review occurred during the creation of the original guideline published in 1996 and included literature published from 1975 through 1994. The second review was conducted for the updated guideline and included literature from 1995 through January 1, 1999. The two reviews were then combined into a single database.

Approximately 6,000 articles were reviewed to identify evaluable literature - 3,000 during the original project and another 3,000 during the update. These articles were obtained through searches of electronic databases and reviews of published abstracts and bibliographies. The appropriateness of an article was determined by applying the criteria for inclusion established a priori by the panel. The criteria were that the article (a) reported the results of a randomized, placebo/comparison controlled trial of a tobacco-use treatment intervention randomized on the patient level, (b) provided followup results at a timepoint at least 5 months after the quit date, (c) was published in a peer-reviewed journal, (d) was published between January 1, 1975 and January 1, 1999; and (e) was published in English. Additionally, articles screened during the update were screened for relevance to economic or health system issues.

NUMBER OF SOURCE DOCUMENTS

Of the 6,000 articles identified from the two reviews, more than 180 articles were identified for possible inclusion in the meta-analysis, and more than 500 additional articles were examined by the panel.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The quality and quantity of empirical support for the recommendation was rated by the following scheme:

A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
B. Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, either few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.
C. Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

The availability of randomized clinical trials was not considered in economic recommendations.

The panel declined to make recommendations when there was no relevant evidence or the evidence considered was too weak or inconsistent.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The literature was reviewed systematically by (a) establishing a priori criteria for relevant studies, (b) reviewing abstracts and articles selected by computer searches and by scanning bibliographies, (c) compiling and reviewing the full articles, (d) compiling evidence tables summarizing these articles, and (e) conducting meta-analyses where possible.

The primary meta-analytic model used in this and the original guideline was logistic regression using random effects modeling. The modeling was done at the level of the treatment arm, and study effects were treated as fixed. The panel methodologists chose to employ random effects modeling, assuming that both the subject populations and the treatment elements analyzed would vary from study to study (e.g., "general problemsolving" counseling might be done somewhat differently at two different sites). Random effects modeling is well suited to accommodate such variation among studies.

The meta-analyses yielded logistic regression coefficients that were converted to odds ratios. Once odds ratios were obtained from meta-analyses, the statistical methodologist estimated 95 percent confidence intervals around the odds ratios. After computing the odds ratios and their confidence intervals, the odds ratios were converted to abstinence percentages and their 95 percent confidence intervals. (Abstinence percentages indicate the estimated long-term abstinence rate achieved under the tested treatment or treatment characteristic.)

The abstinence percentage results essentially duplicate the odds ratio results, but are presented because their meaning may be clearer for some readers.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not stated

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Guideline Panel and consortium members invited 175 outside reviewers to review the current guideline. A total of 70 reviewers provided comments. Peer reviewers included clinicians, health care administrators, social workers, counselors, health educators, researchers, consumers, key personnel at selected Federal agencies, and others. Reviewers were asked to evaluate the guideline based on five criteria: validity, reliability, clarity, clinical applicability, and utility. Comments of the peer reviewers were incorporated into the guideline when appropriate.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summary:

1. Tobacco dependence is a chronic condition that often requires repeated intervention. However, effective treatments exist that can produce long-term or even permanent abstinence.
2. Because effective tobacco dependence treatments are available, every patient who uses tobacco should be offered at least one of these treatments:
    - Patients willing to try to quit tobacco use should be provided treatments identified as effective in this guideline.
    - Patients unwilling to try to quit tobacco use should be provided a brief intervention designed to increase their motivation to quit.
3. It is essential that clinicians and health care delivery systems (including administrators, insurers, and purchasers) institutionalize the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting.
4. Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.
5. There is a strong dose-response relation between the intensity of tobacco dependence counseling and its effectiveness. Treatments involving person-to-person contact (via individual, group, or proactive telephone counseling) are consistently effective, and their effectiveness increases with treatment intensity (e.g., minutes of contact).
6. Three types of counseling and behavioral therapies were found to be especially effective and should be used with all patients attempting tobacco cessation:
    - Provision of practical counseling (problemsolving/skills training);
    - Provision of social support as part of treatment (intra-treatment social support); and
    - Help in securing social support outside of treatment (extra-treatment social support).
7. Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking.
    - Five first-line pharmacotherapies were identified that reliably increase long-term smoking abstinence rates:
        - Bupropion SR
        - Nicotine gum
        - Nicotine inhaler
        - Nicotine nasal spray
        - Nicotine patch
    - Two second-line pharmacotherapies were identified as efficacious and may be considered by clinicians if first-line pharmacotherapies are not effective:
        - Clonidine
        - Nortriptyline
    - Over-the-counter nicotine patches are effective relative to placebo, and their use should be encouraged.
8. Tobacco dependence treatments are both clinically effective and cost-effective relative to other medical and disease prevention interventions. As such, insurers and purchasers should ensure that:
    - All insurance plans include as a reimbursed benefit the counseling and pharmacotherapeutic treatments identified as effective in this guideline; and
    - Clinicians are reimbursed for providing tobacco dependence treatment just as they are reimbursed for treating other chronic conditions.

Specific recommendations:

The strength of evidence (A-C) definitions are repeated at the end of the Major Recommendations.

I. Screening and Assessment

A. Screen for Tobacco Use

All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that this significantly increases rates of clinician intervention. (Strength of Evidence = A)

Clinic screening systems such as expanding the vital signs to include tobacco-use status, or the use of other reminder systems such as chart stickers or computer prompts are essential for the consistent assessment, documentation, and intervention with tobacco use. (Strength of Evidence = B)

B. Specialized Assessment

Once a tobacco user is identified and advised to quit, the clinician should assess the patient's willingness to quit at this time. (Strength of Evidence = C)

- If the patient is willing to make a quit attempt at this time, interventions identified as effective in this guideline should be initiated. (see Chapter 3A and 4 in the guideline document)
- If the patient is unwilling to quit at this time, a motivational intervention should be provided. (see Chapter 3B in the guideline document)

Tobacco dependence treatment is effective and should be delivered even if specialized assessments are not used or available. (Strength of Evidence = A)

II. Treatment Structure and Intensity

A. Advice to Quit Smoking

All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. (Strength of Evidence = A)

All clinicians should strongly advise their patients who use tobacco to quit. Although studies have not independently addressed the impact of advice to quit by all types of nonphysician clinicians, it is reasonable to believe that such advice is effective in increasing their patients' long-term quit rates. (Strength of Evidence = B)

B. Intensity of Clinical Interventions

Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention whether or not he or she is referred to an intensive intervention. (Strength of Evidence = A)

There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. (Strength of Evidence = A)

Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use. (Strength of Evidence = A)

C. Type of Clinician

Treatment delivered by a variety of clinician types increases abstinence rates. Therefore, all clinicians should provide smoking cessation interventions. (Strength of Evidence = A)

Treatments delivered by multiple types of clinicians are more effective than interventions delivered by a single type of clinician. Therefore, if feasible, the delivery of interventions by more than one type of clinician is encouraged. (Strength of Evidence = C)

D. Formats of Psychosocial Treatments

Proactive telephone counseling, and group and individual counseling formats are effective and should be used in smoking cessation interventions. (Strength of Evidence = A)

Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged. (Strength of Evidence = A)

E. Follow-up Assessment and Procedures

All patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. (1) Abstinent patients should receive relapse prevention treatment (see Chapter 3C in the guideline document, For the Patient Who Has Quit). (2) Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. (Strength of Evidence = C):

- If the patient is willing to make another quit attempt, provide or arrange additional treatment (see Chapter 3A in the guideline document, For the Patient Willing To Quit).

- If the patient is not willing to try to quit, provide an intervention to promote motivation to quit (see Chapter 3B in the guideline document, For the Patient Unwilling To Quit).

III. Treatment Elements

A. Types of Counseling and Behavioral Therapies

Three types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problem solving skills/skills training); (2) providing social support as part of treatment; and (3) helping smokers obtain social support outside of treatment. These types of counseling and behavioral therapies should be included in smoking cessation interventions. (Strength of Evidence = B)

Aversive smoking interventions (rapid smoking, rapid puffing, other aversive smoking techniques) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions. (Strength of Evidence = B)

B. Alternative Treatment Models for the Treatment of Tobacco Dependence - Stepped Care and Individual Tailoring

The panel concluded that there is not enough evidence to propose a recommendation regarding (1) a stepped-care model for delivery of tobacco dependence treatment; and (2) individually tailored interventions (e.g., using the transtheoretical model).

C. Pharmacotherapy

All patients attempting to quit should be encouraged to use effective pharmacotherapies for smoking cessation except in the presence of special circumstances. (Strength of Evidence = A)

Long-term smoking cessation pharmacotherapy should be considered as a strategy to reduce the likelihood of relapse. (Strength of Evidence = C)

1. Specific Pharmacotherapies: First-Line Medications

First-line pharmacotherapies have been found to be safe and effective for tobacco dependence treatment and have been approved by the U.S. Food and Drug Administrations (FDA) for this use. First-line medications have established empirical record of efficacy, and should be considered first as part of tobacco dependence treatment except in cases of contraindications.

Bupropion SR (Sustained Release Bupropion)

Bupropion SR is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Nicotine Gum

Nicotine gum is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Clinicians should offer 4 mg rather than 2 mg nicotine gum to highly dependent smokers. (Strength of Evidence = B)

Nicotine Inhaler

The nicotine inhaler is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Nicotine Nasal Spray

Nicotine nasal spray is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

Nicotine Patch

The nicotine patch is an efficacious smoking cessation treatment that patients should be encouraged to use. (Strength of Evidence = A)

2. Specific Pharmacotherapies: Second-Line Medications

Second-line medications are pharmacotherapies for which there is evidence of efficacy for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication; and (2) there are more concerns about potential side effects than exist with first-line medications. Second-line medications should be considered for use on a case-by-case basis after first line treatments have been used or considered.

Clonidine

Clonidine is an efficacious smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. (Strength of Evidence = A)

Nortriptyline

Nortriptyline is an efficacious smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. (Strength of Evidence = B)

Combination Nicotine Replacement Therapy

Combining the nicotine patch with a self-administered form of nicotine replacement therapy (either the nicotine gum or nicotine nasal spray) is more efficacious than a single form of nicotine replacement, and patients should be encouraged to use such combined treatments if they are unable to quit using a single type of first-line pharmacotherapy. (Strength of Evidence = B)

3. Pharmacotherapies Not Recommended by the Guideline Panel
    - Antidepressants other than bupropion SR and nortriptyline
    - Anxiolytics/benzodiazepines/beta-blockers
    - Silver acetate
    - Mecamylamine
4. Over-the-Counter Pharmacotherapeutic Interventions

Over-the-counter nicotine patch therapy is more efficacious than placebo and its use should be encouraged. (Strength of Evidence = B)

IV. Special Populations

A. Gender

The same smoking cessation treatments are effective for both men and women. Therefore, except in the case of the pregnant smoker, the same interventions can be used with both men and women. (Strength of Evidence = B)

B. Pregnancy

Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered extended or augmented psychosocial interventions that exceed minimal advice to quit. (Strength of Evidence = A)

Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective smoking cessation interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)

Pharmacotherapy should be considered when a pregnant woman is otherwise unable to quit, and when the likelihood of quitting, with its

potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking. (Strength of Evidence = C)

C. Racial and Ethnic Minorities

Smoking cessation treatments have been shown to be effective across different racial and ethnic minorities. Therefore, members of racial and ethnic minorities should be provided treatments shown to be effective in this guideline. (Strength of Evidence = A)

Whenever possible, tobacco dependence treatments should be modified or tailored to be appropriate for the ethnic or racial populations with which they are used. (Strength of Evidence = C)

D. Hospitalized Smokers

Smoking cessation treatments have been shown to be effective for hospitalized patients. Therefore, hospitalized patients should be provided smoking cessation treatments shown to be effective in this guideline. (Strength of Evidence = B)

E. Smokers with Psychiatric Comorbidity and/or Chemical Dependency

Smokers with comorbid psychiatric conditions should be provided smoking cessation treatments identified as effective in this guideline. (Strength of Evidence = C)

Bupropion SR and nortriptyline, efficacious treatments for smoking cessation in the general population, also are effective in treating depression. Therefore, bupropion SR and nortriptyline should be especially considered for the treatment of tobacco dependence in smokers with current or past history of depression. (Strength of Evidence = C)

Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore, smokers receiving treatment for chemical dependency should be provided smoking cessation treatments shown to be effective in this guideline, including both counseling and pharmacotherapy. (Strength of Evidence = C)

F. Children and Adolescents

Clinicians should screen pediatric and adolescent patients, and their parents, for tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. (Strength of Evidence = C)

Counseling and behavioral interventions shown to be effective with adults should be considered for use with children and adolescents. The

content of these interventions should be modified to be developmentally appropriate. (Strength of Evidence = C)

When treating adolescents, clinicians may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit tobacco use. (Strength of Evidence = C)

Clinicians in a pediatric setting should offer smoking cessation advice and interventions to parents to limit children's exposure to second-hand smoke. (Strength of Evidence = B)

G. Older smokers

Smoking cessation treatments have been shown to be effective for older adults. Therefore, older smokers should be provided smoking cessation treatments shown to be effective in this guideline. (Strength of Evidence = A)

V. Special Topics

A. Weight Gain After Smoking Cessation

The clinician should acknowledge that quitting smoking is often followed by weight gain. Additionally, the clinician should: (1) note that the health risks of weight gain are small when compared to the risks of continued smoking; (2) recommend physical activities and a healthy diet to control weight; and (3) recommend that patients concentrate primarily on smoking cessation, not weight control, until ex-smokers are confident that they will not return to smoking. (Strength of Evidence = C)

For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT, in particular nicotine gum, which have been shown to delay weight gain after quitting. (Strength of Evidence = B)

B. Non-cigarette Tobacco Products

Smokeless/spit tobacco users should be identified, strongly urged to quit, and treated with the same counseling cessation interventions recommended for smokers. (Strength of Evidence = B)

Clinicians delivering dental health services should provide brief interventions to all smokeless/spit (chewing tobacco and snuff) tobacco users. (Strength of Evidence = A)

Users of cigars, pipes, and other noncigarette combustible forms of tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for smokers. (Strength of Evidence = C)

C. Clinician Training

All clinicians and clinicians-in-training should be trained in effective strategies to assist tobacco users willing to make a quit attempt and to motivate those unwilling to quit at this time. (Strength of Evidence = B)

D. Economic Aspects of Tobacco Dependence Treatments and Health Systems Interventions

The smoking cessation treatments shown to be efficacious in this guideline (both pharmacotherapy and counseling) are highly cost-effective relative to other reimbursed treatments (e.g., treatment of hyperlipidemia and mammography screening) and should be provided to all smokers. (Strength of Evidence = A)

Intensive smoking cessation interventions are especially efficacious and cost-effective, and smokers should have ready access to these services as well as to less intensive interventions. (Strength of Evidence = B)

Smoking cessation treatments (both pharmacotherapy and counseling) should be included as a paid or covered benefit by health benefits plans because doing so improves utilization and overall abstinence rates. (Strength of Evidence = B)

Sufficient resources should be allocated for clinician reimbursement and systems support to ensure the delivery of efficacious tobacco use treatments. (Strength of Evidence = C)

Provision of guideline-based interventions to treat tobacco use and addiction should be included in standard ratings and measures of overall health care quality (e.g., NCQA HEDIS, the Foundation for Accountability [FACCT]). (Strength of Evidence = C)

Definitions of Strength of Evidence Grades:

A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
B. Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, either few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.
C. Reserved for important clinical situations where the panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the guideline document for treating tobacco use.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are primarily based on the published evidence-based research. When the evidence was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants. The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate assessment and treatment of tobacco use and dependence may:

1. Enhance the rates of successful tobacco cessation
2. Decrease the incidence of medical illnesses related to tobacco use
3. Decrease the number of deaths related to tobacco use

POTENTIAL HARMS

- Weight gain related to cessation of tobacco use;
- Exacerbation of comorbid psychiatric conditions following cessation of tobacco use;
- Side effects of pharmacological agents approved by the U.S. Food and Drug Administration (FDA) for smoking cessation:

  Bupropion SR: The most common side effects reported were insomnia (35-40%) and dry mouth (10%).

  Nicotine inhaler: Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.

  Nicotine nasal spray: Nasal/airway reactions. Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste were also reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease. Dependency. Nicotine nasal spray has a dependence potential intermediate between other nicotine-based therapies and cigarettes. About 15-20% of patients report using the active spray for longer periods than recommended, and 5% used the spray at a higher dose than recommended.

  Transdermal nicotine (the nicotine patch): Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but may worsen over the course of

therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In less than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effects include insomnia.

Nicotine chewing gum: Common side effects include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique.

- Side effects of pharmacologic agents not FDA approved for smoking cessation:

  Clonidine: Most commonly reported side effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians may need to monitor blood pressure when using this medication. Rebound hypertension may occur if the dose is not gradually reduced over a period of 2-4 days (rapid increase in blood pressure, agitation, confusion, and/or tremor may occur).

  Nortriptyline: Most commonly reported side effects include sedation, dry mouth (64-78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%).

Subgroups Most Likely to be Harmed:

- Overweight patients
- Patients with comorbid psychiatric conditions
- Precautions in pharmacotherapy should be followed for:
  - Pregnant and lactating women when bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, nicotine patch, clonidine, and nortriptyline are considered
  - Individuals with cardiovascular diseases when nicotine gum, nicotine inhaler, nicotine nasal spray, and nortriptyline are considered.

CONTRAINDICATIONS

CONTRAINDICATIONS

Bupropion SR: This agent is contraindicated in individuals with a history of seizure disorder, a history of an eating disorder, who are using another form of bupropion (Wellbutrin or Wellbutrin SR), or who have used an monoamine oxidase (MAO) inhibitor in the past 14 days.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

1. The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.
2. An absence of studies should not be confused with proven lack of efficacy. In certain situations, there was little direct evidence regarding the efficacy of various treatments, and in these cases the panel usually rendered no opinion. Even when there were enough studies to perform a meta-analysis, a nonsignificant result does not prove inefficacy. Rather, nonsignificance merely indicates that efficacy was not demonstrated given the data available.
3. The emphasis of this guideline was to identify efficacious interventions, not to rank-order interventions in terms of efficacy. The panel chose not to emphasize comparisons among efficacious interventions for several reasons. First, the most important goal of the analytic process was to identify all efficacious interventions. Second, selection or use of particular intervention techniques or strategies is usually a function of practical factors: patient preference, time available, training of the clinician, cost, and so on. The panel believed clinicians should choose the most appropriate intervention from among the efficacious interventions, given existing circumstances. An excessive emphasis on relative efficacy might discourage clinicians from using interventions that have small, but reliable, impact on smoking cessation. Finally, data were often inadequate or unavailable to make adequate statistical comparisons of different types of interventions. For example, there were insufficient studies testing head-to-head comparisons of the different pharmacotherapies to allow a rank-ordering of the different pharmacotherapies.
4. Despite a lack of emphasis on the rank-ordering of interventions, some interventions were so superior to control or no-treatment conditions that the panel clearly identified them as superior to other intervention. For instance, although minimal person-to-person contact can increase smoking abstinence rates over no treatment conditions, there is little doubt that longer person-to-person interventions have greater impact.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Without supportive systems, policies, and environmental prompts, the individual clinician will likely not assess and treat tobacco use consistently. Therefore, just as clinicians must assume responsibility to treat their patients for tobacco use, so must health care administrators, insurers, and purchasers assume responsibility to craft policies, provide resources, and display leadership that results in consistent and effective tobacco use treatment.

Recommendations for Health Care Administrators, Insurers, and Purchasers

Health care administrators and insurers must provide clinicians with assistance to ensure that institutional changes promoting tobacco dependence treatment are implemented universally and systematically. A number of institutional policies would facilitate these interventions such as:

- Implementing a tobacco-user identification system in every clinic (Systems Strategy 1).
- Providing education, resources, and feedback to promote provider intervention (Systems Strategy 2).
- Dedicating staff to provide tobacco dependence treatment and assessing the delivery of this treatment in staff performance evaluations (Systems Strategy 3).
- Promoting hospital policies that support and provide tobacco dependence services (Systems Strategy 4).
- Including tobacco dependence treatments (both counseling and pharmacotherapy) identified as effective in this guideline, as paid or covered services for all subscribers or members of health insurance packages (Systems Strategy 5).
- Reimbursing clinicians and specialists for delivery of effective tobacco dependence treatments and including these interventions among the defined duties of the clinicians (Systems Strategy 6).

Strategy details can be found in the original guideline document. These strategies are based on the evidence presented in the guideline document as well as on panel opinion.

RELATED NQMC MEASURES

- Pneumonia: percent of adult patients with a history of smoking cigarettes who are given smoking cessation advice/counseling during hospital stay.

RELATED QUALITY TOOLS

- You Can Quit Smoking. Follow this 5-Day Countdown to Your Quit Day

- Good Information for Smokers: You Can Quit Smoking

- You Can Quit Smoking. Consumer Guide

- Treating Tobacco Use and Dependence--Clinician's Packet. A How-To Guide For Implementing the Public Health Service Clinical Practice Guideline

- You Can Quit Smoking. Information Kit for Consumers

- Treating Tobacco Use and Dependence—A Systems Approach. A Guide for Health Care Administrators, Insurers, Managed Care Organizations, and Purchasers

- Help for Pregnant Smokers. Support and Advice from Your Prenatal Care Provider. Consumer Tear Sheet

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Department of Health and Human Services, Public Health Services. Treating tobacco use and dependence. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. 197 p. [311 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jun

GUIDELINE DEVELOPER(S)

Public Health Service (U.S.) - Federal Government Agency [U.S.]

GUIDELINE DEVELOPER COMMENT

The updated guideline was sponsored by a consortium of seven Federal Government and nonprofit organizations.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Tobacco Use and Dependence Guideline Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Panel Members: Michael C. Fiore, MD, MPH (Panel Chair); William C. Bailey, MD; Stuart J. Cohen, EdD; Sally Faith Dorfman, MD, MSHSA; Michael G. Goldstein, MD; Ellen R. Gritz, PhD; Richard B. Heyman, MD; Carlos Roberto Jaen, MD, PhD; Thomas E. Kottke, MD, MSPH; Harry A. Lando, PhD; Robert Mecklenburg, DDS, MPH; Patricia Dolan Mullen, DrPH; Louise M. Nett, RN, RRT; Lawrence Robinson, MD, MPH; Maxine L. Stitzer, PhD; Anthony C. Tommasello, MS; Louise Villejo, MPH, CHES; Mary Ellen Wewers, PhD, RN.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panel Members

Michael C. Fiore has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Ciba-Geigy, SmithKline Beecham, Lederle Laboratories, McNeil, Elan Pharmaceutical, and Glaxo Wellcome.

William C. Bailey has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Glaxo Wellcome, SmithKline Beecham, Schering-Plough, 3M Pharmaceuticals, Pfizer, and Sepracor.

Stuart J. Cohen has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Sally Faith Dorfman has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by various pharmaceutical companies.

Michael G. Goldstein, in addition to being an employee of the Bayer Corporation, has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Glaxo Wellcome, McNeil, Ciba-Geigy, SmithKline Beecham, Boehringer Ingelheim, Sano Corporation, Dupont Pharmaceuticals, and Eli Lilly.

Ellen R. Gritz has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Bristol Myers Squibb, SmithKline Beecham, and Glaxo Wellcome.

Richard B. Heyman has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Carlos Roberto Jaén has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Glaxo Wellcome Pharmaceuticals.

Thomas E. Kottke has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by McNeil Consumer Healthcare.

Harry A. Lando has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Glaxo Wellcome and SmithKline Beecham.

Robert Mecklenburg has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by SmithKline Beecham and Glaxo Wellcome.

Patricia Dolan Mullen has not served as a consultant for, given lectures sponsored by, or has conducted research sponsored by any pharmaceutical companies.

Louise M. Nett has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Lawrence Robinson has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Maxine L. Stitzer has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by McNeil and SmithKline Beecham.

Anthony C. Tommasello has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Louise Villejo has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Ortho Biotech.

Mary Ellen Wewers has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Consultants

Timothy Baker has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Elan Pharmaceutical, SmithKline Beecham, Glaxo Wellcome, and Lederle.

Victor Hasselblad has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by CorTheraputics, Skinceuticals, Merck, Novartis, AstraZeneca, AstraCharnwood, The Medicines, Pfizer, Daiichi, Hoffman-LaRoche, RhonePolenc Rorer, Alexion, SmithKline Beecham, Dade, Quad-C, and Centocor Lilly.

Marc Manley has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

David L. Schriger has served as a consultant for, given lectures sponsored by, or has conducted research sponsored by Pfizer Corporation and the MedAmerica Corporation.

David W. Wetter has not served as a consultant for, given lectures sponsored by, or conducted research sponsored by any pharmaceutical company.

Senior Project Staff

Brion J. Fox has not served as a consultant for, given lectures sponsored by, or has conducted research sponsored by any pharmaceutical company.

ENDORSER(S)

American Academy of Pediatrics - Medical Specialty Society
American College of Cardiology Foundation - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

This guideline is an updated version of the 1996 Smoking Cessation Clinical Practice Guideline No. 18 that was sponsored by the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]), U.S. Department of Health and Human Services. The orginal guideline reflected the extant scientific research literature published between 1975 and 1994.

GUIDELINE AVAILABILITY

Print copies: Available by calling (800) 358-9295 or electronically at www.surgeongeneral.gov and the National Library of Medicine's HSTAT database.

AVAILABILITY OF COMPANION DOCUMENTS

The following documents are available:

1. The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives. A clinical practice guideline for treating tobacco use and dependence: a US Public Health Service report. JAMA 2000 Jun 28;283(24):3244-54.
2. Treating tobacco use and dependence. Summary. Rockville (MD): U.S. Department of Health and Human Services. Public Health Service. 2000 Jun.

In addition, a Smoking Cessation Web page is available on the Public Health Service Web site.

PATIENT RESOURCES

The following is available:

- You Can Quit Smoking. Information Kit for Consumers. Rockville (MD): U.S. Department of Health and Human Services. Public Health Services. Clinical Practice Guideline. 2003.

Electronic copies: Available from the Agency for Healthcare Research and Quality.

diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC Summary was completed by ECRI on June 26, 2000. It was reviewed by the guideline developer as of June 27, 2000.

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